K111923 NOV - 4 2011

PT. INTAN HEVEA INDUSTRY

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510k Summary

1.0 Submitter :

Name : PT. INTAN HEVEA INDUSTRY
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Date of Summary Prepared : September 19, 2011

2.0 Contact Person :

Name : Darwin Tandjo
Phone No. : +62-61-6850169, 6856335
Fax No. : +62-61-6850168, 6856335

3.0 Name of the Device :

Trade Name : SKIN GUARD and Multiple or Customer's Trade Name
Device Name : Powder Free Latex Examination Gloves, Non Sterile (contains 50 micrograms/ dm^2 or less of total water extractable protein).
Common Name : Examination Gloves
Classification Name : Patient Examination Gloves (Class I)

4.0 Identification of The Legally Marketed Device (Predicate Device) which Substantially Equivalent:

The Powder Free Latex Examination Gloves, Non Sterile (contains 50 micrograms/dm^2 or less of total water extractable protein) are substantially equivalent with Latex Patient Examination Gloves, Powdered, Non-Sterile submitted and cleared under 510(k) number K894480. The different in this submission is the product Powder Free, Non Sterile with labeling claim contains 50 micrograms/dm^2 or less of total water extractable protein with no change in product design.

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5.0 Description and Specification of The Device :

The Powder Free Latex Examination Gloves, Non Sterile (contains 50 micrograms/dm^2 or less of total water extractable protein) is Class I Device. These gloves are made of natural rubber latex. The gloves can be used either right or left hand (ambidextrous), Disposable, Single Use and Non Sterile. The Specification of this device meets the requirements of ASTM Standard D 3578 – 05 and FDA 1000ml Water Leak Test.

6.0 Intended Use of the Device :

The Powder Free Latex Examination Gloves (contains 50 micrograms/dm^2 or less of total water extractable protein) is a disposable device intended for medical purpose that is worn on the examiners hand and finger to prevent contamination between patient and examiner.

7.0 Summary of The Technological Characteristics of The Device :

The Powder Free Latex Examination Gloves, (contains 50 micrograms/dm^2 or less of total water extractable protein) technological characteristics are summarized in the following information compared with ASTM or equivalent standards ;

Characteristics	Standards	Performance
Dimensions	D 3578 – 05	Meets
Physical Properties	D 3578 – 05	Meets
Freedom from Pinholes	FDA 21 CFR 800.20	Meets
Powder Residue	D 3578 – 05 D 6124 – 06	<2 mg/gloves
Water Soluble Protein Content	D 3578 – 05 D 5712 – 10	< 50µg/dm^2
Biocompatibility	16 CFR Ch.II 1500, 4.1 Primary Skin Irritation in Rabbits	Passes (No primary skin irritation)
	ASTM F720-81 Dermal Sensitization	Passes (No contact sensitizer)

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data :

The performance test data of the non clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

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9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data :

Clinical data is not needed for gloves or for most devices cleared by the 510k process.

10.0 Conclusion :

It can be concluded that the data of Powder Free Latex Examination Gloves, Non Sterile (contains 50 micrograms/dm^2 or less of total water extractable protein) meets ASTM Standards and FDA requirements for water leak test. No skin irritation and skin sensitization detected during the animal study. The data demonstrates Substantially Equivalent and perform as safe, as effective as well as currently marketed devices or predicated device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV - 4 2011

Mr. Darwin Tandjo
Factory Manager
PT. INTAN HEVEA INDUSTRY
Jalan Pulau Irian No.13
Kawasan Industri Medan I
Jalan Yos Sudarso Km 10.5.
Medan 20371
INDONESIA

Re: K111923
Trade/Device Name: POWDER FREE LATEX EXAMINATION GLOVES, NON STERILE
(contains 50 micrograms/dm2 or less of total water extractable protein per gram).
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: October 7, 2011
Received: October 11, 2011

Dear Mr. Tandjo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE.

Applicant : PT. Intan Hevea Industry.

510(k) Number (if known) : K111923

Device Name : POWDER FREE LATEX EXAMINATION GLOVES, NON STERILE (contains 50 micrograms/dm^2 or less of total water extractable protein per gram).

Indications for Use :

Powder Free Latex Examination Gloves, Non Sterile (contains 50 micrograms/dm^2 or less of total water extractable protein) is a disposable device and made of Natural Rubber Latex intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/ OR Over-The-Counter Use V
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON OTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Edith F. Oliveira-Will
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111923